



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/766,608

01/27/2004

Robert F. Rioux

03-226 US

3377

23410 7590 03/20/2009
Vista IP Law Group LLP
2040 MAIN STREET, 9TH FLOOR
IRVINE, CA 92614

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

03/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT F. RIOUX and PAUL DICARLO

Appeal 2008-4680
Application 10/766,608
Technology Center 3700

Decided:¹ March 20, 2009

Before DONALD E. ADAMS, ERIC GRIMES, and MELANIE L.
McCOLLUM, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 2, 4, 7-9, 11, 15, 16, 19, 20, and 68-80. Pending “claims 3, 5, 6, 10, 12-14, 17, 18, and 21-67

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

have been withdrawn from consideration” as directed to a non-elected invention (App. Br. 2). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a system for treating breast tissue. Claims 1, 2, and 4 are illustrative:

1. A system for treating breast tissue, comprising:
a cannula having at least one fluid conveying lumen, the cannula configured for insertion into a breast duct such that the at least one lumen is in fluid communication with the breast duct;
a tissue diagnostic device slidably disposable within the at least one lumen; and
a tissue treatment device slidably disposable within the at least one lumen.
2. The system of claim 1, wherein the tissue diagnostic device comprises a spectrometer.
4. The system of claim 1, wherein the tissue treatment device comprises an ablation electrode.

The Examiner relies on the following evidence:

| | | |
|----------------|-----------------|---------------|
| Hamm | US 5,949,929 | Sep. 7, 1999 |
| Burbank et al. | US 6,497,706 B1 | Dec. 24, 2002 |
| Gatto | US 6,840,909 B2 | Jan. 11, 2005 |

The rejections presented by the Examiner are as follows:

1. Claims 1, 7-9, 11, 15, 19, 20, 68-71, and 76-80 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Gatto.
2. Claims 2, 72, and 75 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Gatto and Hamm.
3. Claims 4, 16, 73, and 74 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Gatto and Burbank.

We affirm.

Anticipation:

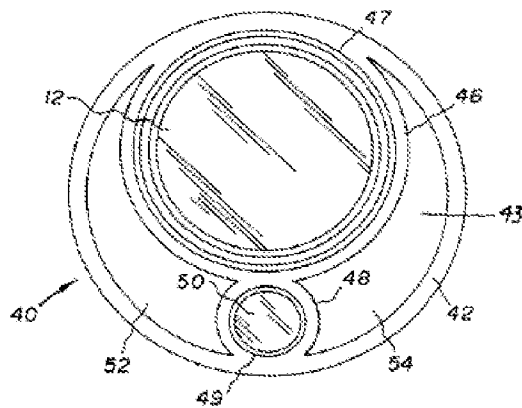
ISSUE

Does Gatto teach a cannula having at least one fluid conveying lumen that is in fluid communication with a breast duct and comprises (1) a tissue diagnostic device and (2) a tissue treatment device slidably disposable within the at least one lumen?

FINDINGS OF FACT

FF 1. Gatto teaches a “micro-endoscope assembly for the removal of tissue and cells from breast ducts” (Gatto, Abstract). For clarity we reproduce Gatto’s Figure 6 below:

Fig. 6



“FIG. 6 is an alternate embodiment of the micro-endoscope assembly invention” (Gatto, col. 5, ll. 60-61).

FF 2. The Examiner finds that

Gatto discloses a system for treating breast tissue, comprising:

a cannula (40 in figure 6) having at least one fluid conveying lumen (43), the cannula configured for insertion into a breast duct such that the at least one lumen is in fluid communication with the breast duct (Abstract);

a tissue diagnostic device (12) slidably disposable within the at least one lumen (47); and

a tissue treatment device (50) slidably disposable within the at least one lumen (49).

(Ans. 3-4.)

FF 3. The Examiner finds that “[b]ecause lumen (47) and lumen (49) are located within lumen (43), . . . [Gatto’s] tissue diagnostic device and the tissue treatment device are both disposable within a lumen that conveys fluid” (Ans. 4).

FF 4. The Examiner finds that the area inside the structure defined by Gatto’s element 42 represents a lumen (e.g., the larger lumen – Gatto’s element 43, which is subdivided into elements 52 and 54 by the additional lumens defined by Gatto’s elements 46/47 and 48/49) (Ans. 6). Thus, as the Examiner explains, “devices placed in lumens (47, 49) can be considered within the larger lumen (43)” (Ans. 6-7).

PRINCIPLES OF LAW

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Analysis of whether a claim is patentable over the prior art under 35 U.S.C. § 102 begins with a determination of the scope of the claim. We determine the scope of the claims in patent applications not solely on the basis of the claim language, but upon giving

claims their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). The properly interpreted claim must then be compared with the prior art.

ANALYSIS

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 is representative.

Appellants' claim 1 is drawn to a system for treating breast tissue. Gatto teaches a "micro-endoscope assembly for the removal of tissue and cells from breast ducts" (FF 1 and 2).

Appellants' claimed system comprises a cannula having at least one fluid conveying lumen. Gatto teaches a cannula (40) having at least one fluid conveying lumen. Specifically, Gatto's cannula (40) has four lumens (47, 49, 52, and 54) (FF 1 and 2; *see also* App. Br. 6 (wherein Appellants concede that Gatto teaches a cannula with four lumens defined by elements 47, 49, 52, and 54)).

As the Examiner explains, the area inside the structure defined by Gatto's element 42 represents a lumen (e.g., the larger lumen – Gatto's element 43, which is subdivided into elements 52 and 54 by the additional lumens defined by Gatto's elements 46/47 and 48/49) (FF 4). We find no error in this interpretation of Appellants' claim 1 or Gatto.

While we recognize that Gatto teaches that endoscope 12 and laser fiber 50 are slidably disposed in lumens 47 and 49 respectively, there is no evidence on this record to support a conclusion that lumens 47 and 49 do *not* remain in fluid communication with the breast duct while the endoscope and

laser fiber are slidably disposed within the lumens. Thus, absent evidence to the contrary, it would appear that Gatto's cannula is configured for insertion into a breast duct such that the at least one lumen is in fluid communication with the breast duct as required by Appellants' claim 1.

Appellants' claim 1 further requires a tissue diagnostic device slidably disposable within the at least one lumen; and a tissue treatment device slidably disposable within the at least one lumen. As the Examiner explains, since "devices placed in lumens (47, 49) can be considered within the larger lumen (43)" Gatto teaches this requirement in Appellants' claim 1 (FF 4).

Appellants do not dispute and therefore concede that Gatto's endoscope 12 and laser fiber 50 meet the requirements of the claimed tissue diagnostic and treatment devices. Further, absent persuasive evidence to the contrary since these devices are slidably disposed within a lumen, it would appear that Gatto's device meets the requirements of Appellants' claim 1, wherein the devices are slidably disposable within the at least one lumen.

Appellants contend that the "pertinent claim language at issue is 'slidably disposable within the at least one [fluid carrying] lumen' (claim[] 1 . . .)" (App. Br. 5). In this regard, Appellants disagree that Gatto's lumens 47 and 49 "are disposed in the fluid conveying lumen 33" (*id.*). Appellants contend that

[T]he only logical way in which a lumen can be disposed within another lumen is if they are in a concentric relationship; that is, one lumen is completely surrounded by the other lumen. Otherwise, the respective lumens will be in a side-by-side arrangement, in which case, the lumens cannot be considered to be disposed in one another.

(App. Br. 6-7.) We are not persuaded. There is no requirement in claim 1 that multiple lumens be disposed within each other in a concentric relationship. To the contrary, claim 1 simply requires that the cannula have at least one fluid conveying lumen. As discussed above, Gatto's cannula meets this requirement.

Appellants contend that Gatto's lumens 47 and 49 are in a "side-by-side relationship with the fluid conveying lumens 52, 54" (App. Br. 7). In this regard, Appellants contend that

As shown in Fig. 6, the lumen 49 in which the laser fiber 50 [is] disposed is completely separate from the fluid conveying lumens 52, 54 (i.e., the two side-by-side half crescent-shaped spaces within sheath 42); that is, the lumen 49 is between the lumens 52, 54. Thus, the laser fiber 50 is not slidably disposed within-but rather slidably disposed between-the fluid conveying lumens 52, 54.

(App. Br. 7.) We are not persuaded. As discussed above, there is no evidence on this record to support a conclusion that lumens 47 and 49 do *not* remain in fluid communication with the breast duct. There is also no persuasive evidence that lumens 47 and 49 are *not* within the larger lumen defined by Gatto's element 42.

We are not persuaded by Appellants' contention regarding "the resulting structure of the Gatto system" wherein "after the Gatto system is assembled, a cylindrical channel 43 no longer exists, but rather has been divided into two lumens 52, 54. Thus, the lumens 47, 49, 52, 54 are not disposed in the non-existent cylindrical channel 43" (Reply Br. 2).

Appellants appear to recognize that the structure defined by Gatto's element 42 produces a lumen 43. Gatto places two additional lumens inside this larger lumen 43. Appellants' claim 1 does not exclude this configuration.

For the foregoing reasons, we are also not persuaded by Appellants' contention that "a device that is disposed i[n] one of the lumens cannot be reasonably construed as being disposed in another of the lumens" (App. Br. 7).

CONCLUSION OF LAW

The preponderance of the evidence on this record supports a conclusion that Gatto teaches a cannula having at least one fluid conveying lumen that is in fluid communication with a breast duct and comprises (1) a tissue diagnostic device and (2) a tissue treatment device slidably disposable within the at least one lumen.

The rejection of claim 1 under 35 U.S.C. § 102(e) as being anticipated by Gatto is affirmed. Claims 7-9, 11, 15, 19, 20, 68-71, and 76-80 fall together with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

Obviousness:

PRINCIPLES OF LAW

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992). On appeal to this Board, Appellants must show that the Examiner has not sustained the required burden. *See* (1) *Ex parte Yamaguchi*, <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd074412.pdf>, slip op. at 5 and 23 (BPAI Aug. 29, 2008) (precedential); (2) *Ex parte Fu*, <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd080601.pdf>, slip op. at 5 and 20 (BPAI Mar. 31, 2008) (precedential); (3) *Ex parte Catan*,

<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd070820.pdf>, slip op. at 3 and 21 (BPAI Jul. 3, 2007) (precedential), and (4) *Ex parte Smith*, <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>, slip op. at 4, 9 and 23 (BPAI Jun. 25, 2007).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, ___, 127 S. Ct. 1727, 1739 (2007).

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at ___, 127 S. Ct. at 1742. It is proper to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at ___, 127 S. Ct. at 1741. *See also id.* at ___, 127 S. Ct. at 1742 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). “In determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

The combination of Gatto and Hamm:

ISSUE

Did Appellants meet their burden of establishing error in the Examiner's prima facie case of obviousness?

FINDINGS OF FACT

FF 5. The Examiner finds that "Gatto discloses a system with all of the aforementioned elements," *see, e.g.* FF 1-4 (Ans. 5).

FF 6. The Examiner finds that "Gatto does not disclose a system, wherein the tissue diagnostic device comprises a spectrometer" (*id.*).

FF 7. The Examiner finds that Hamm "discloses a system wherein the tissue diagnostic device comprises a spectrometer" (*id.*).

ANALYSIS

Based on the foregoing factual findings the Examiner concludes that it would have been prima facie obvious to a person of ordinary skill in this art to incorporate Hamm's spectrometer into Gatto's cannula "in order to analyze the spectroscopic data to determine the probability of a malignancy" (Ans. 5). We find no error in the Examiner's prima facie case.

Appellants contend that "Gatto does not disclose a cannula that has a fluid conveying lumen in which a diagnostic device, imaging device, or a tissue treatment device is slidably disposed, and Hamm does not supplement this failed teaching" (App. Br. 8). For the foregoing reasons we disagree with Appellants' contention.

CONCLUSION OF LAW

Appellants failed to meet their burden of establishing error in the Examiner's prima facie case of obviousness.

The rejection of claim 2 under 35 U.S.C § 103(a) as unpatentable over the combination of Gatto and Hamm is affirmed. Claims 72 and 75 fall together with claim 2. 37 C.F.R. § 41.37(c)(1)(vii).

The combination of Gatto and Burbank:

ISSUE

Did Appellants meet their burden of establishing error in the Examiner's prima facie case of obviousness?

FINDINGS OF FACT

FF 8. The Examiner finds that "Gatto discloses a system with all of the aforementioned elements," *see, e.g.* FF 1-4 (Ans. 5).

FF 9. The Examiner finds that "Gatto does not disclose a system, wherein the tissue treatment device comprises an ablation electrode, which ha[s] two electrodes in a bipolar arrangement" (*id.*).

FF 10. The Examiner finds that Burbank "discloses a system, wherein the tissue treatment device comprises an ablation electrode having two electrodes in a bipolar arrangement" (*id.*).

ANALYSIS

Based on the foregoing factual findings the Examiner concludes that it would have been prima facie obvious to a person of ordinary skill in this art

to incorporate Burbank's ablation electrodes into Gatto's cannula "in order to provide a means for separating and capturing a tissue specimen from the target tissue site" (Ans. 6). We find no error in the Examiner's prima facie case.

Appellants contend that "Gatto does not disclose a cannula that has a fluid conveying lumen in which a diagnostic device, imaging device, or a tissue treatment device is slidably disposed, and Burbank does not supplement this failed teaching" (App. Br. 9). For the foregoing reasons we disagree with Appellants' contention.

In addition, Appellants contend that Burbank's ablation electrodes are [U]sed to cut and capture a tissue specimen from a target tissue site in a biopsy procedure – not to treat the target tissue site. Thus, even if the electrode arrangement disclosed in Burbank could somehow be incorporated into the cannula disclosed in Gatto, the resulting structure would still not include every element required by claim[] 4.

(*Id.*)

In response, the Examiner reasons that

[O]ne of ordinary skill in the art would have been motivated to use the ablation electrodes as an alternative means to immediately remove or ablate suspect tissue when discovered by the system of Gatto. This modification would not change the overall purpose of Gatto, namely, the removal of tissue and cells from an abnormal area The modification is a simple substitution of one means for treatment/resection/biopsy for another and it would have been routine for one having ordinary skill in the art to incorporate the ablation electrodes with the probe of Gatto.

(Ans. 7-8.) We find no error in the Examiner's rationale. In this regard, we are not persuaded by Appellants' unsupported contention that "[i]t is highly

Appeal 2008-4680
Application 10/766,608

doubtful that a physician, or a patient suspected of having breast cancer, would consider a biopsy a form of treatment” (Reply Br. 3).

CONCLUSION OF LAW

Appellants failed to meet their burden of establishing error in the Examiner’s prima facie case of obviousness.

The rejection of claim 4 under 35 U.S.C § 103(a) as unpatentable over the combination of Gatto and Burbank is affirmed. Claims 16, 73, and 74 fall together with claim 4. 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

Vista IP Law Group LLP
2040 MAIN STREET, 9TH FLOOR
IRVINE CA 92614